12.0 510(k) Summary

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. **Name of Manufacturer, Contact Person and Date Summary Prepared:**

Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673
Phone: 949-940-7260
FAX: 949-940-7313
Contact Person: Jimmy Wong, Manager of Clinical and Technical Affairs
Date Prepared: Sept. 3, 2003

2. **Device Name:**

Trade/Proprietary Name:	Nichols Advantage® Cortisol
Device Name:	Cortisol radioimmunoassay
Device Description:	Cortisol (hydrocortisone and hydroxycorticosterone) test system
Classification:	2
Regulation Number:	862.1205
Product Code:	CGR, Clinical Chemistry

3. **Predicate Device:** Diagnostic Product Corporation Coat-A-Count Cortisol

4. **Device Description:**
The Nichols Advantage Cortisol assay contains sufficient reagents for 100 tests. The assay is a chemiluminescent competitive binding assay for cortisol in human serum, plasma, and urine.

5. **Intended Use:**
The Nichols Advantage® Cortisol assay is intended for use with the Nichols Advantage® Specialty System for the quantitative determination of cortisol concentrations in human serum, EDTA plasma and urine. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

6. **Comparison to Predicate Device:**
The Nichols Advantage Cortisol (Y) was compared to the DPC Coat-A-Count Cortisol RIA (X) previously cleared by the FDA (K810891, 4/14/81). One hundred fifty (150) serum samples in which the clinical diagnosis were unknown were assayed in duplicate by both methods following each manufacturers' directions. The range observed with method "X" was 1.9 to 68.2 µg/dL; range for method "Y" was 2.8 to 49.5 µg/dL. Deming regression analysis of these data yielded an equation of Y = 0.70X + 2.5 (95% CI for slope and intercept were 0.67 to 0.73, and 1.9 to 3.2, respectively). Pearson's correlation coefficient (r) of the paired data was 0.97.

7. **Similarities:**

- Specimen type is identical for both methods.
- Both assays use cortisol calibrators, are based upon competitive binding technology, and both report values using the same units: µg/dL.
- Both assays use a specific antibody to cortisol to measure the hormone in serum or plasma samples, and after extraction in urine samples.

8. **Differences:**

The following differences pertain to differences in immunoassay technology and do not affect the intended uses of each assay.

Feature	Nichols Advantage Cortisol	DPC Coat-A-Count Cortisol
Sample Size:	12 µL serum or EDTA plasma and extracted urine	25 µL serum or heparin plasma and extracted urine
Binding Technology	Magnetic particles - avidin coated	Antibody coated tubes
Incubation steps and temperature:	36 minutes @ 37°C	45 minutes @ 37°C
Analytical sensitivity	≤0.8 µg/dL	0.2 µg/dL
Sample Bias	Heparinized values are lower	EDTA values are higher

9. Comparison of Performance Characteristics

Feature	Nichols Advantage Cortisol	DPC Coat-A-Count Cortisol
Within-Run Precision (%CV)	3.6-8.7%	3.0-5.1%
Total Precision (%CV)	7.1-17.4%	4.0-6.4%
Recovery	97-109%	91-100%
Linearity	94-107%	92-101%

Conclusions: These data, which were provided to FDA, demonstrate safety and effectiveness of the Nichols Advantage Cortisol for its intended in vitro diagnostic use. Furthermore, based on performance characteristics, the Nichols Advantage Cortisol assay is substantially equivalent to the predicate method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 9 2004

Mr. Jimmy Wong
Manager, Clinical and Technical Affairs
Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673

Re: k042689
Trade/Device Name: Nichols Advantage Cortisol
Regulation Number: 21 CFR 862.1205
Regulation Name: Cortisol (hydrocortisone and hydroxycorticosterone) test system
Regulatory Class: Class II
Product Code: CGR, JIT
Dated: September 20, 2004
Received: September 29, 2004

Dear Mr. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042689

Device Name: Nichols Advantage Cortisol

Indications For Use:

The Nichols Advantage® Cortisol assay is intended for use with the Nichols Advantage® Specialty System for the quantitative determination of cortisol concentrations in human serum, EDTA plasma and urine. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

The Nichols Advantage Cortisol Assay Calibrators are intended for adjustment of the stored curve for the Nichols Advantage Cortisol assay.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042689